



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6008

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

March 7, 2005

File # 05-NWJ-11

Mr. Clyde Rockoff
President
Universal Nutrition Services
3 Terminal Road
New Brunswick, New Jersey 08901-3615

Dear Mr. Rockoff:

On September 1, 2004, an investigator from this office visited your manufacturing facility located at 3 Terminal Road in New Brunswick, New Jersey. At that time it was determined that you are the manufacturer and distributor of Universal Naturals Daily Caps, a daily multi-vitamin and mineral supplement, Muscle Pro-24™, a bodybuilding supplement, and Uni-Syn MRP2™, a meal replacement powder. Samples of these products were collected on that date and analyzed by the Food and Drug Administration (FDA).

FDA's laboratory analysis of Universal Naturals Daily Caps, lot number [REDACTED] revealed sub-potency in the nutrients: Vitamin A and Folic Acid compared to the amount declared on the label. FDA laboratory results are as follows:

Nutrient	Analysis	Label Declaration	Found	% of Declared	Check Analysis %
Vitamin A	Original	5750 IU or 115% DV	0 IU / 0% DV	0	-
Folic Acid	Original	400mcg or 100% DV	0mcg / 0% DV	0	0

FDA's laboratory analysis of Muscle Pro-24™, lot number [REDACTED] revealed sub-potency in the nutrients: Vitamin B6, Folic Acid, Vitamin C, Vitamin A, and Vitamin E compared to the amount declared on the label. FDA laboratory results are as follows:

Nutrient	Analysis	Label Declaration	Found	% of Declared	Check Analysis %
Vitamin B6	Original	700mcg or 35% DV	152mcg / 7.6% DV	22	21.6
Folic Acid	Original	140mcg or 35% DV	14.2mcg / 3.5% DV	10	10.1
Vitamin C	Original	21mg or 35% DV	1.17mg / 2.8% DV	8	5.6
Vitamin A	Original	1750 IU or 35% DV	0mcg / 0.00 DV	0	0
Vitamin E	Original	10.5 IU or 35% DV	0mcg / 0.00 DV	0	0

Our analysis revealed that your Universal Naturals Daily Caps, lot number [REDACTED] and Muscle Pro-24™, lot number [REDACTED] are adulterated within the meaning of 402(b)(1) in that valuable constituents have been omitted or abstracted therefrom.

Universal Naturals Daily Caps, lot number [REDACTED] and Muscle Pro-24™, lot number [REDACTED] are also misbranded within the meaning of 403(a)(1) of the Act, because the product labels are false or misleading in that the product labels indicate the products contain nutrients at levels that are not present in the products.

The above is not intended to be an all-inclusive list of deviations from the regulations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please note that based on the label for your product Uni-Syn MRP2™, which characterizes this product as a "nutritional supplement" and bears a Supplement Facts label, it appears that you intend to market this product as a dietary supplement. However, the product is represented on the principal display panel as a "meal replacement powder." It is further described as a "meal replacement" in the product description on the information panel. Section 201(ff)(2)(B) of the Act states that the term "dietary supplement" means a product that "is not represented for use as a conventional food or as a sole item of a meal or the diet." Because this product is represented for use as a "meal

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replacement" (i.e., a sole item of a meal or diet), it is not subject to regulation as a dietary supplement but rather as a conventional food. Therefore, your product Uni-Syn MRP2™ is misbranded under section 403(q)(1) of the Act because it does not bear nutrition labeling as required for conventional foods by 21 CFR 101.9.

Moreover, the product Uni-Syn MRP2™ is misbranded within the meaning of section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because the label bears the claim "Low in Sugar". Section 403(a)(1) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the Agency takes into account representations made or suggested by a statement, among other things (see 21 U.S.C. 321(n)). A comparison of the sugar content of your product to comparable products, reveals they contain the same or similar amounts of sugar. Consequently, the "Low in Sugar" claim is false and misleading and therefore violates section 403(a)(1).

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps that you have taken to correct any violations and to assure that similar violations do not occur. Your response should include an explanation of each step being taken to correct the violations, and prevent a recurrence. You may wish to include in your response documentation concerning procedures you have implemented or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above. If you have questions regarding any issue in this letter, please contact Mr. Manney directly.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ray Abraham for", written in dark ink.

Douglas I. Ellsworth
District Director
New Jersey District